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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,799

Applicant(s)

MOCKEL ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 8-47 is/are pending in the application.
- 4a) Of the above claim(s) 12-26 and 28-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5, 8, 11, 37, 43 and 45 is/are allowed.
- 6) ☒ Claim(s) 9, 10, 27, 31, 33-36, 38-42, 44, 46 and 47 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/2/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on September 9, 2003), Applicants filed a response and amendment received on December 2, 2003. Said amendment amended Claims 5, 8-11, and 27, cancelled Claims 1-4, 6, and 7 and added new Claims 31-47. Thus, Claims 5 and 8-47 are pending in the instant Office action. Claims 12-26 and 28-30 remain withdrawn from consideration as non-elected inventions. Claims 5, 8-11, 27, and 31-47 will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the foreign application 100 42 051.6 filed in Germany on August 26, 2000 as requested in the declaration. Receipt was previously acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Applicants have also filed a certified translation of the German priority document.

Information Disclosure Statement

3. The information disclosure statement filed on December 2, 2003 has been reviewed, and its reference has been considered as shown by the Examiner's initials next to each citation on the attached copy.

Withdrawn - Objections to the Specification

4. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.

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5. Previous objection to the specification for being confusing with respect to the sequence listing is withdrawn by virtue of Applicants' amendment to the specification to describe SEQ ID NO:5.

6. Previous objection to the specification for having an inconsistency with respect to the use of the *cstA* gene is withdrawn by virtue of Applicant's amendment to the Abstract.

Withdrawn - Claim Objections

7. Previous objection to Claim 5 for depending from a rejected claim is withdrawn by virtue of Applicants' amendment.

8. Previous objection to Claim 8 for a typographical error is withdrawn by virtue of Applicants' amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claims 1-4, 6-7, and 27 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "from coryneform bacteria" is withdrawn by virtue of Applicants' amendment.

10. Previous rejection of Claims 1-4, 6-7, and 27 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "which codes for the *cstA* gene" is withdrawn by virtue of Applicants' amendment.

11. Previous rejection of Claim 2 under 35 U.S.C. § 112, second paragraph, is withdrawn by virtue of Applicants' cancellation of said claim.

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12. Previous rejection of Claim 7 under 35 U.S.C. § 112, second paragraph, is withdrawn by virtue of Applicants' cancellation of said claim.

13. Previous rejection of Claims 9-10 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "**the** cstA gene" (emphasis added) is withdrawn by virtue of Applicants' amendment to require a specific cstA gene sequence.

14. Previous rejection of Claims 9-10 under 35 U.S.C. § 112, second paragraph, as being indefinite for the metes and bounds of the enhanced gene is withdrawn by virtue of Applicants' amendment removing the term "enhanced".

15. Previous rejection of Claim 11 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "A shuttle vector *Escherichia coli* DH5alphamcr/pED-K18mob2cstAexp" is withdrawn by virtue of Applicants' amendment.

16. Previous rejection of Claims 1-4, 6, 7, and 27 under 35 U.S.C. 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation and amendment specifically reciting the exact structure of the cstA gene in Claim 5 and amending Claim 27 to depend from Claim 5.

17. Previous rejection of Claims 9-10 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' amendment specifically reciting the exact structure of the cstA gene (by way of the genus of encoding SEQ ID NO:2) in Claim 9.

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18. Previous rejection of Claims 1-4, 6, 7, 9-10, and 27 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' cancellation of amendment to specifically recite an exact sequence or genus of exact sequences in the claims.

19. Previous rejection of Claims 1-4, 6, 7, 9-10, and 27 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' cancellation of amendment to specifically recite an exact sequence or genus of exact sequences in the claims.

20. Previous rejection of Claim 11 under 35 U.S.C. § 112, first paragraph, enabling deposit, is withdrawn by virtue of Applicant's amendment to the specification to include the full address of the depository as well as by virtue of Applicant's statement of irrevocability made in the remarks filed on December 2, 2003.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

21. Previous rejection of Claims 1-4, 6-10, and 27 under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.* is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims as well as by virtue of Applicant's filing of a certified translation of the priority document teaching the invention of the instant claims.

22. Previous rejection of Claims 1-4, 6-10, and 27 under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims as well as by virtue of Applicant's filing of a certified translation of the priority document teaching the invention of the instant claims.

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23. Previous rejection of Claims 1-3, 6, and 7 under 35 U.S.C. § 102(b) as being anticipated by Cole *et al.* is withdrawn by virtue of Applicant's cancellation of said claims.

NEW ISSUES

All previous issues have been withdrawn for the reasons noted above.

Claim Objections

24. Claim 32 is objected to for a typographical error. The word "isolate" should be --- isolated---. Correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25. Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "vector which carries a polynucleotide" is unclear as the term "carries" is not a term of the art. The Examiner suggests replacing this term with ---comprises--- for clarity.

26. Claim 31 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "said polynucleotide is native to *Corynebacterium glutamicum*" is

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confusing in reference to Claim 5. Firstly, SEQ ID NO:1 was isolated from *C. glutamicum*, so if this phrase is meant to further limit the nucleic acid sequence, it is incapable of doing that since the sequence is exactly limited in Claim 5. If the phrase were meant to limit the entire polynucleotide claimed, this would require the entire polynucleotide be native to *C. glutamicum*, i.e., the entire chromosome where SEQ ID NO:1 is found. This interpretation seems unlikely. Clarification is required.

27. Claims 33-35 and 46 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “carbon starvation protein A activity” is unclear. This rejection was previously set forth against Claim 2. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants argue that, in view of Accession Number P15078 wherein a description of *cstA* as having the function of “peptid utilization during carbon starvation”, the phrase is clear. The Examiner disagrees. What kind of activity is peptide utilization? Is any reaction catalyzed? Does *cstA* interact with certain proteins, wherein a complex has some effect? For one of skill in the art to be able to recognize the genus claimed, the encoded protein’s activity must be clear. Clarification is required.

The Examiner notes that Claim 33 requires the polynucleotide to encode SEQ ID NO:2. Since the encoding language defines the genus of sequences and since SEQ ID NO:2 has an inherent activity, the phrase “carbon starvation protein A activity” is not necessary in the claims. The Examiner suggests deleting it from Claim 33. This deletion will not correct the error for Claim 36.

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28. Claims 39-40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 39, the phrase “a complete complement of SEQ ID NO:1” is unclear since only a single species must be ---the complete complement of SEQ ID NO:1. Can shorter versions be included to broaden the term to a genus instead of the species? Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

29. Claims 38 and 46 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In Claim 38, the recitation of **100-2515** of SEQ ID NO:1 does not have support in the specification as originally filed. The sequence listing describes the open reading frame (coding sequence) as **200-2515**. Applicants are required to remove the new matter from the specification or to cite clear support for the alleged new matter in response to the instant Office action.

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30. Claims 31, 35, and 46 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 31 is drawn to a polynucleotide wherein the polynucleotide is native to *Corynebacterium glutamicum*; Claim 35 is drawn to a polynucleotide wherein the polynucleotide is isolated from *Corynebacterium glutamicum*.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

In the specification, a single example of a *cstA* gene from *C. glutamicum* that meets the structural limitations of Claims 5 and 33 is described. No examples of other *C. glutamicum* sequences are described, either *cstA* sequences or general *C. glutamicum* sequences. The instant claims are drawn to a subgenus of all *cstA* genes within the claimed structural limitations, wherein the polynucleotide must be from *C. glutamicum* – this includes sequences such as allelic variants. The specification does not describe *C. glutamicum* *cstA* sequences to the exclusion of *cstA* sequences from other sources. Clearly, *cstA* sequences from *C. glutamicum* within the structural limitations are enabled by the disclosure; however, one of skill in the art would be unable to recognize other members of the claimed subgenus to the exclusion of *cstA* genes from

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E. coli, within the structural limitations. Thus, the claimed subgenus does not have adequate written description. The Examiner suggests the deletion of the phrase “native to (or isolated from) *C. glutamicum*” to obviate the instant rejection. Since these are the only added limitations in these claims, the Examiner suggests cancellation of said claims.

31. Claims 36 and 46 are rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 36 is drawn to polynucleotides related to SEQ ID NO:1 by definite hybridization conditions wherein the encoded protein has a particular function; however, that function is unclear as noted above.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses polynucleotides related to SEQ ID NO:1. Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations (which is unclear). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having an unclear function. Applicants have not fully described a genus that has sequence identity limitations in the absence of clear functional limitations.

This issue was previously presented to Applicants. Inclusion of the functionality of the encoded polypeptide is considered to be Applicants' response. This response would have obviated this rejection had the phrase "carbon starvation protein A activity" been considered clear (see above).

32. Claims 10 and 46 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for overexpression using copy number or strong promoters, does not reasonably provide enablement for overexpression using other means indicated in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make the claimed product commensurate with the claimed scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404).

Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

In the specification on pages 11-12 (paragraph [0040]), means of overexpression are described. Said means include not only increasing the copy number of a gene or regulating the gene with a particular promoter, which means are enabled by the art, but also include altering the ribosome binding site, altering the lifetime of the mRNA, altering the protein so as to prevent degradation, and altering media conditions, all of which are known in the art to "overexpress" a gene in specific examples, but none of which are predictable with *cstA* or other genes that lack specific examples in the art. The specification provides no working examples or direction for overexpression using means of ribosome binding site, altering the lifetime of the mRNA, altering the protein so as to prevent degradation, and altering media conditions. The nature of the invention is that these means are specific to a particular gene sequence and cannot be extrapolated from other, unrelated genes; there is no particular recipe of media that will

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overexpress all genes. Thus, overexpression using these methods is wholly unpredictable and not enabled by the specification or the art.

33. Claims 36 and 46 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for any polynucleotide encoding SEQ ID NO:2 (a *cstA* gene), does not reasonably provide enablement for polynucleotides encoding polypeptides wherein the polynucleotide hybridize under low stringency conditions as cited in Claim 36. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make the claimed product commensurate with the claimed scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized above.

The instant specification teaches SEQ ID NO:2, a carbon starvation protein from *C. glutamicum*, and SEQ ID NO:1, a *C. glutamicum* gene exactly encoding SEQ ID NO:2. The art includes few examples of *cstA* encoding genes, with carbon starvation being mostly studied in *E. coli*. The art fully enables any DNA encoding SEQ ID NO:2 based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other *cstA* genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotide products within the scope of the claims because the ability to find a *cstA* gene, which is structurally related to SEQ ID NOs:1 and/or 2, is not equivalent to the ability to make a *cstA* gene as required by the statute (i.e., “make and use”). No description in the specification or the art provides particular residues whose encoding is

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important within the disclosed sequence so that its *cstA*-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

This issue was previously presented to Applicants. Other claims, such as Claims 33-35, obviate this issue because of the limited genus of structures having to encode SEQ ID NO:2. Claim 36 has not such requirement.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

34. Claims 9, 41, 42, 44, 46, and 47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Eikmanns *et al.* (see IDS) as evidenced by GenBank Accession Number BX927149 (see attached PTO-892). The instant claims are drawn to recombinant coryneform bacteria that contain SEQ ID NO:1.

Eikmanns *et al.* teach recombinant *C. glutamicum* cells; all *C. glutamicum* cells inherently contain SEQ ID NO:1, a gene native to *C. glutamicum* as evidenced by GenBank Accession Number BX927149.

The Examiner notes that, in the instant claims, no requirement that the recombinant nature of the bacteria be the result of addition of SEQ ID NO:1. Moreover, the isolated polynucleotide is structurally identical to the non-isolated one inherently found in *C. glutamicum* naturally.

35. Claims 33-35, 38, 42, and 46 are rejected under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.* (WO 01/00804 - -see IDS). The instant claims are drawn to polynucleotides similar to a nucleic acid encoding SEQ ID NO:2 and *C. glutamicum* that overexpress the *cstA* gene.

Pompejus *et al.* teach SEQ ID NO:13 that exactly encodes the full-length of the protein SEQ ID NO:2 in the instant application (see previously attached alignment). SEQ ID NO:13 of Pompejus *et al.* is identical to a portion of SEQ ID NO:1 except for an insert of 13 nucleotides prior to the coding sequence (200-2515bp); moreover, SEQ ID NO:13 of Pompejus *et al.* does not include the first 86 nucleotides of the coding sequence for SEQ ID NO:2. Pompejus *et al.* describe this sequence as encoding a carbon starvation protein (see Table 1, page 56). Pompejus *et al.* also teach overexpression of SEQ ID NO:13 in *C. glutamicum* to produce lysine using overexpression vectors (see page 8).

The Examiner notes that Claims 33-35, 42, and 46 cannot be afforded the foreign priority date because the foreign priority document does not have support for 81% or 91% identical to SEQ ID NO:1. Moreover, Claim 38 is also not supported by the priority document.

36. Claims 33-35, 38, 42, and 46 are rejected under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790 - -see IDS). The instant claims are drawn to polynucleotides

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similar to a nucleic acid encoding SEQ ID NO:2 and *C. glutamicum* that overexpress the cstA gene.

Nakagawa *et al.* teach SEQ ID NO:7061, a portion of which wholly and exactly encodes SEQ ID NO:2 in the instant application (see previously attached alignment); Nakagawa *et al.* also teach SEQ ID NO:727 that encodes a portion of SEQ ID NO:2 (see previously attached alignment). SEQ ID NO: 7061 of Nakagawa *et al.* is identical to SEQ ID NO:1 except for an insert of 13 nucleotides prior to the coding sequence (200-2515bp). Nakagawa *et al.* describe SEQ ID NO:727 as encoding a carbon starvation protein (see Table 1, page 72). Nakagawa *et al.* also teach overexpression of the disclosed sequences in *C. glutamicum* to produce the encoded polypeptides (see page 22).

The Examiner notes that Claims 33-35, 42, and 46 cannot be afforded the foreign priority date because the foreign priority document does not have support for 81% or 91% identical to SEQ ID NO:1. Moreover, Claim 38 is also not supported by the priority document.

Other Relevant Art

37. The following is cited to complete the record for the reasons noted:

- a) USPAP 2002/0197605, filed on December 18, 2000 (Nakagawa *et al.*) is related to EP 1108790.

Summary of Pending Issues

38. The following is a summary of the issues pending in the instant application:

- a) Claim 32 stands objected to for a typographical error.
- b) Claim 27 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "carries".

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- c) Claim 31 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “said polynucleotide is native to *Corynebacterium glutamicum*”.
- d) Claims 33-35 and 46 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “carbon starvation protein A activity”.
- e) Claims 39-40 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “a complete complement of SEQ ID NO:1”.
- f) Claims 38 and 46 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
- g) Claims 31, 35, and 46 stand rejected under 35 U.S.C. § 112, first paragraph, written description (native to).
- h) Claims 36 and 46 stand rejected under 35 U.S.C. 112, first paragraph, written description (structure without clear function).
- i) Claims 10 and 46 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement (overexpression).
- j) Claims 36 and 46 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement (breadth of structure not enabled).
- k) Claims 9, 41, 42, 44, 46, and 47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Eikmanns *et al.* as evidenced by GenBank Accession Number BX927149.
- l) Claims 33-35, 38, 42, and 46 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.*
- m) Claims 33-35, 38, 42, and 46 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.*

Conclusion

39. Claims 5, 8, 11, 37, 43, and 45 are allowable; Claim 32 is objected to; Claims 9, 10, 27, 31, 33-36, 38-42, 44, 46, and 47 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. The instant Office action is **NON-FINAL**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Examiner
Art Unit 1652

February 18, 2004